

Embassy of Malaysia

3516 International Court NW
Washington DC 20008
Tel: (202) 572-9710/9734
Fax: (202) 572-9782

FAX

To: Mr Matthew Eckel
Office of International Programs
Food and Drug Administration

From: Seng Foo Wong
E-mail: mltimydc@erols.com

Fax: 301 - 827 0003

Pages: 4

Phone: 301 - 827 0907

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c.c. Ms Julia Ho, Director for Asia and Pacific, US FDA (Fax: 301 - 827 0033)

Bioterrorism Act 2002

We are pleased to forward herewith a copy of the letter from Hon. Rafidah Aziz the Minister of International Trade and Industry of Malaysia to Hon. Ambassador Zoellick, the USTR outlining Malaysia's concerns on various aspects of the Bioterrorism Act 2002 which can have serious implications on Malaysia's food exports to the United States of America.

Malaysia understands the need for the Bioterrorism Act. However, in developing the regulations to implement the Act, it is our hope that the US Administration particularly the FDA and the Department of Health and Human Services would address the specific areas of concern raised by Malaysia.

The Embassy of Malaysia is particularly appreciative of the recent opportunity to participate in the FDA discussions with foreign embassies and stakeholders. We certainly look forward to future consultations and discussions with the FDA in finalizing the guidelines and regulations in implementing the Act.

Thank you.


Seng Foo Wong
Minister - Counsellor (Economics)
Embassy of Malaysia
Washington DC

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MINISTER OF INTERNATIONAL TRADE AND INDUSTRY
MALAYSIA

BPA (O) 1221

11 October 2002

H.E Robert Zoellick
US Trade Representative
United States of America

Dear Amb Zoellick,

BIOTERRORISM ACT 2002

I would like to draw your attention to the Bioterrorism Act signed by President Bush in June 2002. I am concerned with the implementation of the Act that may have serious implications on Malaysia's food exports to the United States.

2. Malaysia's concern on specific sections of the Act include:

- i. Section 303 - The duration of detention of imported goods should be as short as possible to avoid additional costs and delayed entry of products into the US market.
- ii. Section 304 - The debarred US food importers should be made known to Malaysian exporters to avoid detention of shipments.



- iii. **Section 305** - The deadline for registration of food additives was 9 September 2002 while the deadline for registration of food facilities is 12 December 2003. Though the deadlines have been set, there is no explicit information on the registration process. Malaysian exporters should be informed of the procedures for registration in order to comply with the regulation. In addition, sufficient notice should be given on effective dates of implementation to avoid unnecessary detention at the ports of entry. Application for registration should also be considered and approved within a reasonable time frame and reasons for rejection should be made known. I urge the US authorities to officially notify the date of enforcement of new regulations and provide sufficient grace period to Malaysian exporters to facilitate compliance.
- iv. **Section 307** - The notification process particularly for major US importers appears to be tedious and time consuming and this may discourage them from importing abroad. The process should be simple and hassle-free.
- v. **Section 322** - The type of analysis required is not stated and Malaysia may not have adequate and appropriate facilities to undertake the testing. The requirement for a certificate of analysis and bond would result in additional costs.



4. Malaysia understands the need for the Bioterrorism Act 2002. However, the Act should not impede trade between our two countries. Complicated and excessively strict inspection process would affect the competitiveness of Malaysian products and may discourage US traders from importing Malaysian products.

5. I hope the United States would consider Malaysia's concerns and ensure that the Implementation of the Act does not create unnecessary obstacles to international trade and add further cost of doing business between our two countries.

Thank you.

Yours Sincerely,

A handwritten signature in black ink, which appears to read 'Rafidah'. The signature is written in a cursive style and is underlined.

(RAFIDAH AZIZ)